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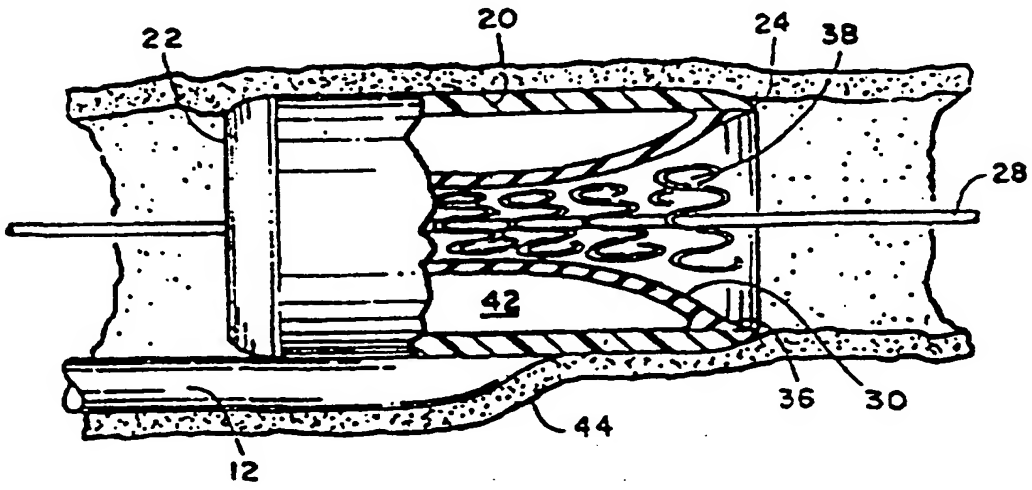

(57) Abstract

A device and method for retrieving a stent from the vessel of a patient includes a catheter which is formed with a central lumen that defines a passageway having a diameter. A deformable distal tip is attached to the catheter to establish an extension of the passageway. In the operation of the device, the distal tip is initially maintained in a first configuration wherein the stent can be received into and through the passageway. While the distal tip is maintained in this first configuration, a portion of the stent to be retrieved is withdrawn into the passageway of the distal tip. The distal tip is then distended or deformed into a second configuration wherein the diameter of the passageway is reduced to grip the stent. The catheter and the gripped stent are then retrieved from the vessel of the patient.

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STENT RETRIEVAL DEVICE

Field of the Invention

The present invention relates generally to a method and device for stent retrieval.

Background of the Invention

Many kinds of stents are quite frequently used in cardiovascular surgery for the purpose of providing a supporting structure for anatomical vessels. More specifically, stents are often placed at the site of a stenosis in a vessel to establish and maintain the patency of the vessel. This, of course, may be necessary in order to allow for the continued flow of blood through the vessel. Not surprisingly, the deployment and accurate placement of a stent in the vessel of a patient requires a great deal of skill.

As difficult as it may be to deploy and emplace a stent, the effort required to retrieve a misplaced stent can be equally as difficult, if not more so. To appreciate this, first consider how a stent is placed in a vessel such as an artery. Typically, the stent is deployed into the vessel of a patient with the stent mounted over the balloon of a balloon catheter. As so mounted, the stent is passed through a previously positioned guiding catheter and to the desired location in the vessel. Actual placement of the stent in the vessel is then accomplished by extending the stent and

balloon catheter beyond the distal end of the guiding catheter where the balloon can then be inflated at the target site. This balloon inflation extends the stent and then separates the stent from the balloon upon balloon deflation. At this point, if, as sometimes can happen, trouble is encountered in delivering the stent to the target site prior to deployment, the stent should be retrieved. The retrieval of a stent from a body vessel necessarily requires the engagement of a retrieval instrument with the stent. Ideally, because the placement catheter is already in place, the stent can be withdrawn into the placement catheter and then removed from the vessel without stent dislodgement. Engagement of the placement catheter with the stent, however, can be troublesome. Specifically, during withdrawal of the stent into the placement catheter, it can happen that the stent snags on the catheter. Most often, this snagging occurs at or near the distal end of the placement catheter. Further, the problem can be aggravated by the presence of a relatively soft distal tip which it typically attached to the distal end of the catheter to reduce trauma to the patient.

Should the stent become snagged or the distal end of the catheter, the balloon, which has only the ability to expand the stent, will be of little value in retrieving the stent. On the other hand, the present

invention recognizes that the placement catheter may, itself, be helpful in accomplishing the task of retrieving the stent.

In light of the above, it is desired to provide a device for retrieving a stent from the vessel of a patient which can grip onto and hold the stent during its removal from the vessel. Additionally, it is desired to provide a device for retrieving a stent from the vessel of a patient which is simple to use, relatively easy to manufacture and comparatively cost effective.

Summary of the Preferred Embodiments

A device for retrieving a misplaced stent from the vessel of a patient includes a catheter which is formed with a central lumen. This central lumen defines a passageway which is dimensioned with a diameter that initially allows the stent to pass through the passageway of the catheter for emplacement in a vessel when the stent is in a collapsed configuration. Importantly, the device also includes a soft distal tip that is attached to the distal end of the catheter.

In the preferred embodiment of the device for the present invention, the distal tip is formed with a chamber that is established between a relatively rigid outer wall and a relatively flexible inner wall. As

oriented on the device, the flexible inner wall surrounds and defines a portion of the passageway. Relative to the inner wall, the outer wall is located outwardly and radially therefrom. Additionally, an inflation means is engageable with the catheter to connect the inflation means in fluid communication with the chamber in the distal tip via an inflation lumen in the catheter.

In an alternate embodiment of the device for the present invention, the distal tip is also formed with a compartment that is located distally from the chamber. With structure that is reversed but somewhat similar to that of the chamber, the compartment is established between a relatively flexible outer panel and a relatively rigid inner panel. Like the chamber, the compartment in the distal tip can be placed in fluid communication with the inflation means.

In the operation of the device of the present invention, the guiding catheter is initially positioned in the vessel of a patient for placement of a stent into the vessel. A balloon catheter is then provided, with the stent to be deployed, collapsed and positioned over the deflated balloon. The collapsed stent is then passed through the central lumen of the device and deployed into the vessel at the site where it is to support the vessel.

If, for some reason, the delivery of the stent is unsuccessful and the stent snags upon attempted withdrawal into the guiding catheter, the proximal end of the stent is withdrawn into that portion of the passageway which is surrounded by the distal tip until resistance is felt. The inflation means is then activated to inflate the chamber. With this inflation of the chamber, the relatively flexible inner wall distends. This, in turn, reduces the diameter of the passageway and causes the distal tip of the catheter to grip onto the stent. The device can then be withdrawn from the vessel along with the stent that is being gripped by its distal tip while the guiding wire remains in the body vessel.

To facilitate entry of the stent into the guiding catheter, as indicated above, the distal tip of the catheter can be further formed with a compartment which is located distally from the chamber. Inflation of this compartment by the inflation means distends the flexible outer panel of the compartment and causes the extreme distal portion of the distal tip to flare. This flaring facilitates withdrawal of the stent into the passageway of the catheter. This maneuver alone may allow complete stent retrieval. If the stent snags despite this, however, the chamber can then be inflated in the manner as indicated above, to grip the stent.

In either case, the device with the gripped stent is then withdrawn from the patient.

The present invention provides a device and method for retrieving stents from within a body conduit such as a vein or artery. While the preferred use of the invention is to retrieve coronary stents, use in retrieving stents from other body conduits is contemplated and is explicitly within the scope of the invention.

This can be accomplished by side mounting a stent retriever tube having inner inflatable balloons over the proximal end of a balloon catheter shaft, compressing the tube thereby decreasing the profile, advancing the tube through the guide catheter to the stent, allowing the tube to recover its full profile, pulling a slight vacuum on the inner balloons, advancing the tube over the stent, inflating the inner balloons, grasping the stent, and withdrawing the stent into the guide catheter. While the preferred embodiment mounts over a balloon catheter shaft, the invention may be mounted over other shafts, including guide wires, and may be used without any shaft at all. The preferred embodiment is advanced within a guide catheter, but advancement within other elongate tubes is contemplated and is also within the scope of the invention.

In one embodiment, the retrieval device includes an elongate shaft having a longitudinally slit tube mounted at the distal end. The preferred tube includes a metal (e.g., stainless steel, super-elastic alloy) spine and rib cage having a polymeric sheath bonded to the interior, exclusive of the slit. The tube further includes at least one inflatable inner balloon, attached near the interior wall of the tube. The preferred embodiment has two or more inflatable balloons. The shaft preferably includes hypotube in fluid communication with the inflatable balloons. While tubular shaped balloons are preferred, running substantially the length of the tube, other sized balloons, including a concentric, double walled, inflatable sleeve, is contemplated for use as the balloon. The transition from tube to shaft includes a shoulder, preferably formed of polymeric material. When inflation fluid is supplied to the inflatable balloons, the balloons increase in diameter, decreasing the effective inside diameter of the tube, grasping and compressing any stent within the tube, enabling the capture and withdrawal of a stent.

In use, the slit tube is mounted over a shaft lying within a guide catheter, such as a stent placement balloon shaft. The tube is compressed by curling one side of ribs inside the other side of ribs

near the tube slit. The tube is advanced through the guide catheter, exiting the guide catheter distally, and allowed to recover its original profile. The tube is advanced over the stent, and inflation fluid is supplied to inner balloons, decreasing the effective inside diameter, grasping and compressing the stent. The tube grasping the stent is then withdrawn into and through the guide catheter and out of the patient.

Brief Description of the Drawings

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

Figure 1 is a perspective view of the retrieval shuttle of the present invention;

Figure 2 is a cross-sectional view of the shuttle body of the present invention taken along the lines marked 2-2 in Figure 1;

Figure 3 is a cross-sectional view of the shuttle body of the present invention taken along the lines marked 3-3 in Figure 1;

Figure 4 is a cross-sectional view of the shuttle body of the present invention as shown in Figure 2,

with the flexible bladder now shown in a collapsed configuration;

Figure 5 is a partial cut-away of the retrieval shuttle of the present invention shown operationally positioned in the vessel of a patient;

Figure 6 is a cross-sectional view of an alternate embodiment for the shuttle body of the present invention; Figure 7 is a perspective view of the device of the present invention;

Figure 8 is a perspective view of the distal portion of the device of the present invention shown with a stent on a balloon catheter extending beyond the distal tip of the present invention;

Figure 9 is a perspective view of the present invention, as shown in Figure 8, with the device engaged onto a stent for withdrawal or retrieval of the stent from the vessel of a patient;

Figure 10 is a cross sectional view of the distal tip of the present invention with stent and balloon catheter removal as would be seen along the line 10-10 in Figure 7;

Figure 11 is a cross sectional view of the distal tip of the present invention as shown in Figure 10 with the distal tip gripping a stent as shown in Figure 9;

Figure 12 is a cross sectional view of the distal tip of the present invention as seen along the line 12-12 in Figure 7;

Figure 13 is a cross sectional view of an alternate embodiment of the distal tip of the present invention as would be seen along the line 10-10 in Figure 7;

Figure 14 is a cross sectional view of the catheter of the present invention, which can be used with the alternate embodiment of the distal tip, as seen along the line 14-14 in Figure 7;

Figure 15 is a cross sectional view of the distal tip of the alternate embodiment of the present invention as shown in Figure 13 with the compartment of the distal tip distended;

Figure 16 is a cross sectional view of the distal tip of the alternate embodiment of the present invention as shown in Figure 13 with the chamber of the distal tip distended.

Figure 17 illustrates a fragmentary side view of a slit tube grasping device having inflatable inner balloons;

Figure 18 is a cross-section projection view of the device of Figure 17, taken along 18-18;

Figure 19 illustrates a highly diagrammatic, perspective view of a partially deployed stent, balloon catheter, and guide catheter;

Figure 20 further illustrates the perspective view of Figure 19, including the stent retrieval device of Figure 17 before stent capture and before tube profile recovery;

Figure 21 further illustrates the perspective view of Figure 19, including the stent retrieval device of Figure 17 before stent capture after profile recovery; and

Figure 22 further illustrates the perspective view of Figure 19, including the stent retrieval device of Figure 17 after stent capture.

Detailed Description of the Preferred Embodiment

Referring initially to Figure 1, the retrieval shuttle of the present invention is shown and generally designated 10. In general terms, it may be seen that the retrieval shuttle 10 includes a positioning catheter 12 having a proximal end 14 and a distal end 16. A connector 18 is attached to the proximal end 14 of the positioning catheter 12. Preferably, the positioning catheter 12 is formed from a relatively rigid but somewhat resilient and flexible material such as polyester or hypodermic-type tubing.

The present invention also includes a shuttle body 20. The shuttle body 20 is formed from a substantially rigid material, such as polyester or metal and is attached to the distal end 16 of the positioning catheter 12. The shuttle body 20 has a proximal end 22 and a distal end 24.

Additionally, the shuttle body is formed to surround a lumen 26 which passes between the distal end 24 and the proximal end 22 of the shuttle body 20. Figure 1 also shows that the present invention is intended to be usable in combination with a guidewire 28.

The structural details of the present invention are more easily appreciated by reference to Figures 2 and 3. In Figures 2 and 3, it may be seen that the flexible bladder 30 is positioned inside of the lumen 26 of the shuttle body 20. The flexible bladder 30 is formed to surround a passageway 32 and has a proximal end 34 and a distal end 36. The proximal end 34 of the flexible bladder 30 is circumferentially sealed to the proximal end 22 of the shuttle body 20. Similarly, the distal end 36 of the flexible bladder 30 is circumferentially sealed to the distal end 24 of the shuttle body 20. Also, the passageway 32 of the flexible bladder 30 is dimensioned so that the stent 38 may be received into the passageway 32 of the flexible

bladder 30. In Figure 3, it is seen that the flexible bladder 30 is positioned coaxially with respect to shuttle body 20 and that placement catheter 12 is in fluid communication with chamber 40 that is established between bladder 30 and shuttle body 20. It is to be appreciated that the present invention is intended to be usable for the retrieval of a wide range of stents, like stent 38, as well as a wide range of medical prosthesis and other foreign objects. It is also to be appreciated that the present invention is specifically intended to be usable in vessels of varying size. As a result, the present invention specifically envisions that retrieval shuttle 10, and passageway 32 may be fabricated over a range of useful dimensions.

Turning now to Figure 4, it may be seen that a pressurizable chamber 40 is formed between the shuttle body 20 and the flexible bladder 30. Additionally, it may be seen in both Figures 3 and 4 that the positioning catheter 12 is formed with a lumen 42 and that lumen 42 of the positioning catheter 12 is attached in fluid communication with the pressurizable chamber 40. Functionally, a source of fluid pressure (not shown) is attached to the connector 18 at the distal end of the positioning catheter 12. The fluid travels through the lumen 42 of the positioning catheter 12 to pressurize the chamber 40.

Pressurization of the chamber 40 applies pressure to the flexible bladder 30 causing the flexible bladder 30, and the passageway 32 of the flexible bladder 30 to progressively collapse.

The ability of the flexible bladder 30 to progressively collapse may be better appreciated by comparison of Figure 2 and Figure 4. More specifically, it may be seen in Figure 2 that the flexible bladder 30 is substantially uncollapsed. By comparison, in Figure 4, the passageway 32 of the flexible bladder 30 has distended radially inward, partially collapsing flexible bladder 30. Importantly, it may be seen in Figure 2 that the stent 38 is physically smaller than the passageway 32 of the flexible bladder 30. As a result, the stent 38 is free to move within the flexible bladder 30. In contrast, in Figure 4, the passageway 32 of the flexible bladder 30 has partially collapsed around the stent 38. As a result, the stent 38 is held in the flexible bladder 30.

Operation of the present invention, as best seen in Figure 5, begins with insertion of the distal end 16 of the positioning catheter 12 and shuttle body 20 into the vessel of a patient. The positioning catheter 12 is then manipulated to progressively advance the shuttle body 20 through the vessel, until the shuttle

body 20 is adjacent to the stent 38 or other removal target. In many cases, advancement of the shuttle body 20 will be facilitated by use of a prepositioned guidewire, such as the guidewire 28. In cases of this type, the guidewire 28 is inserted through the lumen 26 of the shuttle body 20 and the shuttle body 20 is advanced over the guidewire 28 until the target to be removed has been reached.

Once the shuttle body 20 has reached the stent 38, the positioning catheter is further manipulated to advance the shuttle body 20 over the stent 38 until stent 38 is partially or fully contained in the lumen 26 of the shuttle body 20. This may be more fully appreciated by reference to Figure 3 where it may be seen that the shuttle body 20 and distal end 16 of the positioning catheter 12 have been advanced through a vessel 44 to position the stent 38 partially inside of the lumen 26 of the shuttle body 20.

Fluid is then passed through the lumen 42 of the positioning catheter 12, pressurizing the chamber 40 that is formed between the lumen 26 of the shuttle body 20 and the flexible bladder 30. The pressurization causes the passageway 32 of the flexible bladder 30 to progressively collapse, or deform, to surround and hold the stent 38. The deformation of the flexible bladder 30 is clearly shown in Figure 5, where it may be seen

that the flexible bladder 30 has collapsed to surround the stent 38. With the flexible bladder 30 collapsed to hold the stent 38, the positioning catheter 12 is manipulated to withdraw the shuttle body 20 and the stent 38 from the patient, completing the procedure.

Turning now to Figure 6, an alternative embodiment of the retrieval shuttle is shown and generally designated 10'. As shown in Figure 6, retrieval shuttle 10' includes the same positioning catheter 12 and shuttle body 20 as retrieval shuttle 10 of Figure 2. For retrieval shuttle 10', however, flexible bladder 30 of Figure 2 has been replaced by flexible bladder 46. More specifically, it may be seen that flexible bladder 46 has a proximal end 48 and a distal end 50. Unlike flexible bladder 24, however, the distal end 50 of flexible bladder 46 is sealed. Additionally, the proximal end 48 of flexible bladder 46 is connected in fluid communication to the lumen 42 of the positioning catheter 12. Functionally, fluid passes from the fluid pressure source (not shown) through the positioning catheter 12 and into the flexible bladder 46. The passage of fluid into the flexible bladder 46 causes the flexible bladder 46 to expand to selectively occupy the lumen 26 of the shuttle body 20.

Operation of the retrieval shuttle 10' generally follows the same sequence of steps utilized in the case of retrieval shuttle 10. In the case of retrieval shuttle 10' however, the removal target is received into the lumen 26 of the shuttle body 20 to be adjacent to the flexible bladder 46. The flexible bladder 46 is then selectively expanded by operation of the fluid pressure source to trap the removal target between the expanded flexible bladder 46 and the lumen 26 of the shuttle body 20. The positioning catheter 12, shuttle body 20 and removal target are then removed from the patient completing the procedure.

Referring to Figure 7, a device for retrieving a stent from the vessel of a patient is shown and is generally designated 120. As shown, the device 120 includes an elongated catheter 122 having a distal tip 124 which is attached thereto by any means well known in the pertinent art, such as by bonding. Additionally, the device 120 includes an inflation unit 126 which is engageable with the catheter 122 for purposes to be more fully disclosed below. To accomplish the intended tasks of the present invention, the catheter 122 is preferably made of Teflon® duralin material and the distal tip 124 is made of a relatively elastic material such as latex. It will be appreciated by the skilled artisan, however, that other bio-

compatible materials are suitable for the manufacture of the catheter 122 or the distal tip 124.

Figure 7 also shows that the catheter 122 is formed with a central lumen 128 which creates a passageway 130. Though not shown in its entirety, it is to be understood that the passageway 130 extends the entire length of the catheter 122 from the proximal end 132 of catheter 122 to its distal end 134. As further indicated in Figure 7, distal tip 124 is attached to this distal end 134 of catheter 122 and the passageway 130 extends from the catheter 122 through the (soft) distal tip 124.

In Figure 8, a balloon catheter 136 is shown extending past the distal tip 124 of the catheter 122. More specifically, the balloon catheter 136 is shown with a balloon 138 and a stent 140 which has been positioned around the balloon 138 of balloon catheter 136. As shown in Figure 8, the stent 140 is in a collapsed configuration and the balloon 138 is deflated. Additionally, a guidewire 142 is shown which can be used, if desired, to assist in the placement of both the device 120 and balloon catheter 136 in a manner that is well known in the pertinent art.

As indicated above in the Background of the Invention, it is an object of the present invention to retrieve the stent 140 from the vessel of a patient

(not shown) when the delivery or placement of the stent 140 in the vessel has been unsuccessful. Unsuccessful delivery of the stent 140 can always be detected while the stent 140 remains in its collapsed configuration (shown in Figure 8). If unsuccessful, it is desirable that device 120 be able to retrieve stent 140. In accordance with the present invention, this retrieval is accomplished by having the distal tip 124 of device 120 grip onto the stent 140 in a manner as substantially shown in Figure 9.

The structural aspects of distal tip 124 which allow the device 120 to grip stent 140 will, perhaps, be best understood by now referring to Figure 10. There it will be seen that distal tip 124 is formed with a chamber 144 which is in fluid communication with an inflation lumen 146 that is formed in catheter 122. Further, as indicated in Figure 7, it is to be appreciated that the inflation lumen 146 is connected directly into fluid communication with the inflation unit 126 via a line 148 in any manner well known in the art. As stated above, distal tip 124 is made of a relatively elastic material which is capable of being stretched when subjected to pressure.

Still referring to Figure 10, it will be seen that the chamber 144 is established and located between an inner wall 150 and an outer wall 152. Further, the

inner wall 150 surrounds that portion of passageway 130 which extends through distal tip 124. Importantly, this inner wall 150 is more flexible, and thus more susceptible to stretching, than is the outer wall 152. This is so because, as shown, inner wall 150 is thinner than is the outer wall 152. Consequently, when inflation unit 126 is activated to increase fluid pressure in chamber 144, the inner wall 150 will distend in a manner substantially as shown in Figure 11. This distention of inner wall 150 then decreases the diameter of passageway 130 in distal tip 124 from a distance 154 (shown in Figure 10) to a distance 154' (shown in Figure 11). With this decrease in the distance 154, distal tip 124 is capable of gripping onto the portion of stent 140 that is then located in passageway 130 of distal tip 124. For a more complete appreciation of the structure of device 120 which forms chamber 144 in distal tip 24, refer to Figure 12. There it will be noted that chamber 144 completely surrounds the passageway 130. Thus, a distention of distal tip 124 will result in a gripping of stent 140 from all radial directions.

In an alternate embodiment of the present invention, the catheter 122 is modified to include a distal tip 156 which includes a compartment 158. Figure 13 is illustrative of this alternate embodiment

and best shows the structural modifications which distinguish the distal tip 156 from the distal tip 124 shown in Figure 10. As shown in Figure 13, the compartment 158 of distal tip 156 is located distally from the chamber 144 and is, in all essential respects, the same as the chamber 144 previously disclosed for distal tip 124. The main difference between the two being a reversal in the radial location of the thicker and thinner members.

In Figure 13 it will be seen that the compartment 158 is formed by an inner panel 160 which is radially inside and radially distanced from an outer panel 162. Also seen in Figure 13 is the fact that the outer panel 162 is thinner, and thus more susceptible to stretching, than is the inner panel 160. Further, it can be appreciated by cross referencing Figure 13 with Figure 7 that the inflation unit 126 is connected via line 164 with an inflation lumen 166 which places the inflation unit 126 in fluid communication with the compartment 158. As is to be appreciated by reference to Figure 14, both inflation lumens 146 and 166 run the length of catheter 122.

Figure 15 indicates that when the compartment 158 is inflated by the inflation unit 126, the outer panel 162 tends to expand relative to inner panel 160. This differential expansion between outer panel 162 and

inner panel 160 which occurs upon inflation of compartment 158 causes the outer panel 162 of distal tip 156 to distend. Importantly, this distension of outer panel 162 also prompts the distal tip 156 to flare in a manner that causes the distance 168 (shown in Figure 13) to increase to the distance 168' (shown in Figure 15). As will be appreciated by cross referencing Figures 15 and 16, the compartment 158 of distal tip 156 can be inflated separately from the inflation of chamber 144. On the other hand, it will also be appreciated that both the compartment 158 and the chamber 144 of distal tip 156 can be simultaneously inflated.

To consider the operation of the preferred embodiment of the device 120 of the present invention, it is to be assumed that the stent 140 has somehow been unsuccessfully positioned into the vessel of a patient. To retrieve the misplaced stent 140, the stent is withdrawn until contact is made with the distal tip 124 of catheter 122, and until the distal tip 124 surrounds a portion of the stent 140, such as is shown in Figure 9. Inflation unit 126 is then activated to increase fluid pressure in chamber 144. This increase in pressure causes distal tip 124 to distend and to grip onto the stent 140, such as is shown in Figure 10. While distal tip 124 grips the stent 140, the catheter

122 with gripped stent 140 can be withdrawn from the patient and thereby retrieved without dislodgement.

In the operation of the alternate embodiment of the present invention, the distal tip 158 of device 120 is advanced into contact with the stent 140 much the same is disclosed above for the preferred embodiment. Upon contact with stent 140, however, in order to facilitate engagement of the device 120 with stent 140, the extreme distal end portion of distal tip 158 can be flared by inflating compartment 158. This flare is intended to allow further unhindered advancement of the distal tip 158 over the stent 140. Then, as before, if necessary, the chamber 144 is inflated to distend a portion of the tip 158 (see Figure 16) and grip onto the stent 140. Again, the stent 140 is retrieved with the device 120.

Figure 17 illustrates a stent retrieval device 220 embodying the present invention including a tube portion 246 and a shaft portion 222, tube 246 being attached to a distal region of shaft 222, and having a proximal shoulder 230 decreasing in diameter from tube 246 to shaft 222. A preferred embodiment includes a longitudinal slit 240 running the entire length of tube 246 and through shoulder 230 for side mounting tube 246 over a shaft. Tube 246 can be mounted over the proximal region of a balloon catheter shaft extending

proximally from a guide catheter within the patient. In a preferred embodiment, tube 246 includes radial reinforcing ribs 236 joined to a longitudinal spine 234. In a preferred embodiment, there are three ribs.

In one embodiment, tube 246 has a slight taper over its length, having a larger inside diameter distally then proximally. This aids in stent withdrawal by presenting a smaller profile to the guide catheter distal end upon withdrawal while presenting a larger inside diameter to the stent to be captured.

A preferred method of making ribs 236 and spine 234 is to laser cut a piece of NITINOL tubing, for example, 0.063 inch outside diameter tubing having 0.004 inch wall thickness. The laser cutting leaves spine 234 and ribs 236 as a single piece.

Shaft 222 can be fixedly attached to spine 234 at spine stem 252 by soldering, as indicated at 254. In a preferred embodiment, shaft 222 is formed of stainless steel hypotube which includes inflation lumen 224.

A preferred embodiment of tube 246 has a tube interior sheath 244 forming the inner wall of tube 246. Sheath 244 substantially covers the inside of tube 246 including ribs 236 and spine 234, but not covering slit 240. In a preferred embodiment, sheath 244 is formed by bonding angioplasty balloon material within the

interior of tube 246, leaving slit 240 open. The most preferred sheath material is polyolefin or fluoropolymer. The most preferred method of bonding sleeve to ribs utilizes adhesive.

One embodiment has a single inner balloon within tube 246. The most preferred embodiment has two inner balloons 238, within tube 246. In the most preferred embodiment, balloon 238 is bonded along a side to the interior of sheath 244, holding balloon 238 away from tube center. Balloon 238 is in fluid communication with inflation lumen 224.

The preferred embodiment includes a shoulder collar 232 over shoulder 230, providing a transition from tube 246 to shaft 222. In one embodiment, shoulder 230 is conical shaped. In a most preferred embodiment, shoulder 230 has a contour as illustrated in Figure 17. In a preferred embodiment, shoulder collar 232 is formed from polyolefin or fluoropolymer. Shoulder collar 232 can be formed by wrapping a piece of polymeric material over shoulder 230 and bonding it in place using adhesive.

A preferred embodiment includes a distal receiver 242 attached to the distal region of tube 246. Distal receiver is preferably tapered, having a larger inside diameter at the distal-most end than at the proximal-most end. In the preferred embodiment, distal receiver

242 is flares as illustrated in Figure 17. Distal receiver 242 can be made from the same material as inner sheath 244, and may be formed in one piece with inner sheath 244. Distal receiver 242 serves to guide and center a stent relative to tube 246 center during stent capture.

Figure 18 illustrates a cross section taken through the distal portion of tube 246 distal to the distal-most rib 236. Ribs 236 are shown divided into long rib 260 and short rib 262 by slit 240. In a preferred embodiment, slit 240 is not located directly opposite spine 234. In a most preferred embodiment, slit 240 is located 90 degrees relative to spine 234. Sheath 244 is interior to ribs 236 in the preferred embodiment. Shoulder collar 232 is shown in background in Figure 18.

Balloons 238 are shown in both deflated state 238a and inflated state 238b in Figure 18. When tube 246 is advanced toward the stent, balloons 238 are deflated, preferably under a small vacuum. When tube 246 has advanced over the stent to be captured, balloons 238 are pressurized, decreasing the effective inside diameter of the tube, thereby grasping and compressing the captured end of the stent.

In use, when a balloon catheter is positioned in the patient within a guide catheter, having a stent

near the balloon, the distal region of a stent retrieval device is side mounted over a proximal region of the catheter shaft laying outside the patient, and compressed to fit within the guide catheter if necessary. The grasping device portion of the retrieval device is advanced into the patient, distally out of the guide catheter, to the stent. The stent is then grasped by inflating the inner balloons, and pulled back into the guide catheter and withdrawn from the patient.

Figures 19-22 illustrate the problem and its solution by the present invention. The embodiment of Figure 17 is shown for example, in highly diagrammatic form.

Figure 19 illustrates a guide catheter 300, including a distal end 302, having an inflatable balloon catheter 307 inserted therethrough, including a catheter shaft 310, and balloon 308. Stent 304 is shown, having slipped proximally from the desired, mid-balloon position. Distal slippage presents a similar problem. Stent 304 includes a proximal end 306. As shown, withdrawing balloon catheter 307 into guide catheter 300 presents the possibility of guide catheter distal end 302 pushing stent 304 distally off balloon 308. Even in situations where stent 304 has an outer diameter small enough to fit within guide catheter 300,

the possibility of guide catheter 300 dislodging stent 304 upon catheter withdrawal remains. This possibility exists if device catheter shaft 322 is not sufficiently centered within guide catheter 300, thereby allowing stent to be withdrawn proximally while off-center. Such an off-center withdrawal can allow stent 304 to be pushed distally by part of guide catheter distal end 302.

In the preferred method of stent retrieval, tube 246 is side mounted over catheter shaft 310 using slit 240, and is reduced in cross sectional area by compressing ribs 236, forcing ribs on one side of slit 240 radially inward, curling tube 246, causing short ribs 262 and long ribs 260 to overlap one another near slit 240. Tube 246 is thereby curled around shaft 310. Tube 246 is advanced distally over the balloon catheter shaft by advancing device shaft 222, through the guide catheter, exiting the guide catheter distal end. Upon exiting the guide catheter, tube 246 is free to expand its original, larger, inside diameter. In a preferred embodiment, ribs 236 are made of NITINOL, which allows tube 246 to return to its original diameter when warmed to body temperature.

Figure 20 illustrates the stent retrieval device embodiment of Figure 17, distal of guide catheter distal end 302. The device is shown prior to full

profile recovery. Figure 21 illustrates the stent retrieval device embodiment of Figure 17, distal of guide catheter distal end 302. The device is shown, having recovered the full profile present prior to insertion into the guide catheter. As illustrated in Figure 21, the device distal region is sufficiently large enough to contain stent proximal end 306.

With the aid of radiographic visualization, tube 246 is advanced until tube distal receiver 242 surrounds stent proximal end 306. In the preferred method, a slight vacuum is pulled on balloons 238 to increase the effective inside diameter of tube 246. Tube 246 is further advanced, with distal receiver 242 guiding stent 304 into the center axis of the tube. With the stent at least partially within tube 246, inflation fluid pressure is applied, inflated balloons 238 to position 238b as illustrated in Figure 18. The increased balloon profile decreases the effective inside diameter available to the stent, thereby grabbing and compressing the stent. With the stent firmly grasped as illustrated in Figure 22, tube 246 is withdrawn proximally toward the guide catheter distal end. Shoulder 230 is drawn first into the guide catheter, centering tube 246 within the guide catheter and presenting a smooth contour for withdrawal. As device shaft 222 is stronger in tension than

compression, a larger profile for tube 246 and a larger amount of friction is more tolerable during device withdrawal than device advancement. Tube 246 is further withdrawn, exiting the patient's body and the guide catheter.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A device for retrieval of a foreign object from the vessel of a patient, said device comprising:

a positioning catheter formed with a lumen, said positioning catheter having a distal end and a proximal end;

a shuttle body attached to said distal end of said positioning catheter for movement therewith, said shuttle body formed from a substantially rigid material to surround a lumen; and

inflatable means positioned in said lumen of said shuttle body and attached in fluid communication with said lumen of said positioning catheter for selective inflation thereof to hold said foreign object in said lumen of said shuttle body.

2. A device as recited in claim 1 wherein said shuttle body is formed as a tube.

3. A device as recited in claim 1 wherein said lumen of said shuttle body is dimensioned to receive a vascular stent.

4. A device as recited in claim 1 wherein said inflatable means comprises a flexible bladder, said flexible bladder having a proximal end and a distal end.

5. A device as recited in claim 4 wherein said distal end of said flexible bladder is closed and said proximal end of said flexible bladder is connected in fluid communication to said lumen of said positioning catheter to allow fluid to be passed through said positioning catheter to inflate said flexible bladder.

6. A device as recited in claim 4 wherein said proximal end of said flexible bladder is circumferentially sealed to said proximal end of said shuttle body and said distal end of said flexible bladder circumferentially sealed to said distal end of said shuttle body to form a chamber between said flexible bladder and said shuttle body, said chamber pressurizable to selectively expand said flexible bladder to surroundingly hold said foreign object.

7. A device for retrieval of a foreign object from the vessel of a patient, said device comprising:

a positioning catheter, said positioning catheter having a distal end and a proximal end;

a substantially rigid shuttle body formed with a lumen, said shuttle body attached to said distal end of said positioning catheter for movement therewith;

a flexible bladder positioned in said lumen of said shuttle body, said bladder formed to surround a passageway with said passageway of said flexible bladder being dimensioned to receive said foreign object therein, and said flexible bladder being selectively collapsible to surroundingly hold said foreign object in said passageway of said bladder; and

means for collapsing said flexible bladder.

8. A device as recited in claim 5 wherein said passageway of said flexible bladder is dimensioned to receive a vascular stent.

9. A device as recited in claim 5 wherein said shuttle body is formed as a bladder.

10. A device as recited in claim 5 wherein said shuttle body is formed to establish a chamber between shuttle body and said flexible bladder, said chamber being pressurizable to selectively collapse said flexible bladder.

11. A device as recited in claim 9 wherein said positioning catheter is formed with a lumen, said lumen of said positioning catheter being attached in fluid communication with said chamber.

12. A device as recited in claim 10 wherein said means for collapsing said passageway of said flexible bladder includes a fluid pressure source, said fluid pressure source connected to said lumen of said positioning catheter, said fluid pressure source controllable to pressurize said chamber to selectively collapse said flexible bladder.

13. A device for retrieval of a foreign object from the vessel of a patient, said device comprising:

a substantially rigid shuttle body, said shuttle body formed to surround a lumen and having a proximal end and a distal end;

a flexible bladder formed to surround a passageway, said passageway of said flexible bladder dimensioned to receive said foreign object, said flexible bladder having a proximal end and a distal end, said flexible bladder positioned inside said lumen of said shuttle body, said proximal end of said flexible bladder circumferentially sealed to said proximal end of

said shuttle body, said distal end of said flexible bladder circumferentially sealed to said distal end of said shuttle body to form a chamber between said flexible bladder and said shuttle body, said chamber pressurizable to selectively collapse said flexible bladder to surroundingly hold said foreign object; and

a flexible positioning catheter, said positioning catheter attached to said shuttle body, said positioning catheter formed with a lumen, said lumen attached in fluid communication with said chamber.

14. A device as recited in claim 12 further comprising a fluid pressure source, said fluid pressure source connected to said lumen of said positioning catheter, said fluid pressure source controllable to pressurize said chamber to selectively collapse said flexible bladder.

15. A device as recited in claim 12 wherein said passageway of said flexible bladder is dimensioned to receive a vascular stent.

16. A method for retrieving a foreign object from the vessel of a patient, said method comprising the steps of:

providing a device which comprises a positioning catheter formed with a lumen, said positioning catheter having a distal end and a proximal end, a shuttle body attached to said distal end of said positioning catheter for movement therewith, said shuttle body formed from a substantially rigid material to surround a lumen, and

inflatable means positioned in said lumen of said shuttle body and attached in fluid communication with said lumen of said positioning catheter for selective inflation thereof to hold said foreign object in said lumen of said shuttle body;

advancing said device in said vessel to reach said foreign object;

further advancing said device to position said foreign object in said lumen of said shuttle body;

selectively inflating said inflatable means to hold said foreign object; and

withdrawing said device and said foreign object from said vessel.

17. A device for retrieving a stent from a vessel which comprises:

a catheter formed with a central lumen, said central lumen defining a passageway having a diameter;

a distal tip attached to said catheter to surround a portion of said passageway, said tip being formed with a chamber; and

inflation means connected in fluid communication with said chamber to enlarge said chamber and distend said distal tip to decrease said diameter of said passageway at said distal tip to grip a portion of said stent for retrieval of said stent from the vessel.

18. A device as recited in claim 17, wherein said catheter is formed with an inflation lumen, said inflation lumen being in fluid communication with said chamber and said inflation means.

19. A device as recited in claim 18, wherein said inflation means is a fluid pump.

20. A device as recited in claim 17, wherein said tip includes an outer wall and an inner wall with said chamber therebetween.

21. A device as recited in claim 20, wherein said inner wall is more flexible than said outer wall to provide for greater distention of said inner wall relative to said outer wall.

22. A device as recited in claim 17, wherein said distal tip is formed with a compartment, said compartment being located distal from said chamber, and wherein said inflation means is connected in fluid communication with said compartment to enlarge said compartment and distend said distal tip to increase said diameter of said passageway to facilitate retrieval of said stent from the vessel.

23. A device as recited in claim 22, wherein said tip includes an outer panel and an inner panel with said compartment therebetween.

24. A device as recited in claim 23, wherein said outer panel is more flexible than said inner panel to provide for greater distention of said outer panel relative to said inner panel.

25. A device as recited in claim 17, wherein said distal tip is made of latex.

26. A device as recited in claim 17, wherein said catheter is made of a Teflon duralin material.

27. A device for retrieving a stent from a vessel which comprises:

a catheter formed with a central lumen, said central lumen defining a passageway for receiving said stent therein;

a distal tip attached to said catheter to surround a portion of said passageway, said distal tip being deformable between a first configuration wherein said stent can pass through said passageway of said distal tip and a second configuration wherein said distal tip is distended to grip said stent and hold said stent in said passageway for retrieval of said stent from the vessel; and

means engageable with said distal tip for deforming said distal tip.

28. A device as recited in claim 27, wherein said distal tip includes an outer wall and an inner wall with a chamber therebetween, said outer wall being located radially outward from said inner wall with said inner wall being adjacent said passageway.

29. A device as recited in claim 28, wherein said passageway has a diameter defined by said inner wall and said inflation means is in fluid communication with said chamber for distending said distal tip and decreasing said diameter of said passageway to grip said stent with said distal tip.

30. A device as recited in claim 29, wherein said inner wall is more flexible than said outer wall to provide for greater distention of said inner wall relative to said outer wall.

31. A device as recited in claim 29, wherein said distal tip is made of latex.

32. A device as recited in claim 29, wherein said catheter is made of a Teflon® duralin material.

33. A method for retrieving a stent from a vessel of a patient which comprises the steps of:

inserting a device into the vessel, said device including a catheter formed with a central lumen defining a passageway for receiving said stent therein, a distal tip attached to said catheter to surround a portion of said passageway, said distal tip being deformable between a first configuration wherein said

stent can pass through said passageway of said distal tip and a second configuration wherein said distal tip is distended to grip said stent, and an inflation means is engageable with said distal tip for deforming said distal tip;

withdrawing at least a portion of said stent into said passageway of said distal tip;

deforming said distal tip from said first configuration and into said second configuration; and

retrieving said catheter with said stent from the vessel.

34. A method as recited in claim 33, wherein said distal tip includes an outer wall and an inner wall with a chamber therebetween, said outer wall being located radially outward from said inner wall with said inner wall being adjacent said passageway and wherein said passageway has a diameter defined by said inner wall and said inflation means is in fluid communication with said chamber for distending said distal tip and decreasing said diameter of said passageway to grip said stent with said distal tip.

35. A method as recited in claim 34, wherein said inner wall is more flexible than said outer wall to

provide for greater distention of said inner wall relative to said outer wall.

36. A method as recited in claim 35, wherein said distal tip of said catheter is formed with a compartment and said method further comprises the step of inflating said compartment to flare said distal tip for facilitating said withdrawing step.

37. A stent retrieval device comprising:

an elongate shaft including a distal region;

a tube having an effective inside diameter, said tube operatively attached to said shaft distal region; and

means for decreasing said tube effective inside diameter.

38. A stent retrieval device as recited in claim 37, wherein said means for decreasing said effective inside diameter includes at least one inflatable balloon.

39. A stent retrieval device comprising:

an elongate shaft having an inflation lumen and a distal region;

a tube, said tube operatively attached to said shaft distal region;

an inflatable balloon within said tube, said balloon being in fluid communication with said shaft inflation lumen.

40. A stent retrieval device as recited in claim 39, wherein said tube includes a longitudinal slit.

41. A stent retrieval device as recited in claim 40, wherein said tube includes a proximal shoulder extending proximally from said tube proximal region to said shaft, decreasing proximally in outer diameter.

42. A stent retrieval device as recited in claim 41, wherein said slit is substantially linear.

43. A stent retrieval device as recited in claim 42, wherein said tube includes a plurality of reinforcing ribs.

44. A stent retrieval device as recited in claim 43, wherein said tube includes a distal region, said device further comprising

a distal receiver, said receiver operatively attached to said tube distal region and tapered, having

a distal-most inside diameter greater than a proximal-most inside diameter, and

a tube proximal shoulder extending proximally from said tube proximal region to said shaft, decreasing proximally in outer diameter.

45. A method for retrieving a stent comprising:

providing a stent retrieval device including an elongate shaft having a distal region, a retrieval tube operatively attached to said shaft distal region, said retrieval tube having at least one inflatable balloon attached within said tube interior, said retrieval tube decreasing in effective inside diameter when said balloon is inflated;

providing a patient having an elongate tube inserted intravascularly and extending proximally therefrom, having a

stent positioned near the distal end of said elongate tube;

advancing said retrieval tube distally into said patient;

advancing said retrieval tube distal end past said elongate tube distal end;

advancing said retrieval tube distal end until a portion of said stent proximal end is within said retrieval tube distal end,

decreasing said retrieval tube effective inside diameter;

retracting said retrieval tube containing said stent proximally.

46. A method as recited in claim 45, wherein said elongate tube is a guide catheter.

47. A method as recited in claim 46, wherein said guide catheter has a balloon catheter inserted therethrough, further comprising selecting a section of balloon catheter shaft proximal to said patient's body and moving said retrieval tube over said catheter shaft.

48. A method as recited in claim 47, wherein said retrieval tube has a longitudinal slit therethrough, further comprising selecting a section of balloon catheter shaft proximal to said patient's body and moving said retrieval tube slit over said catheter shaft.

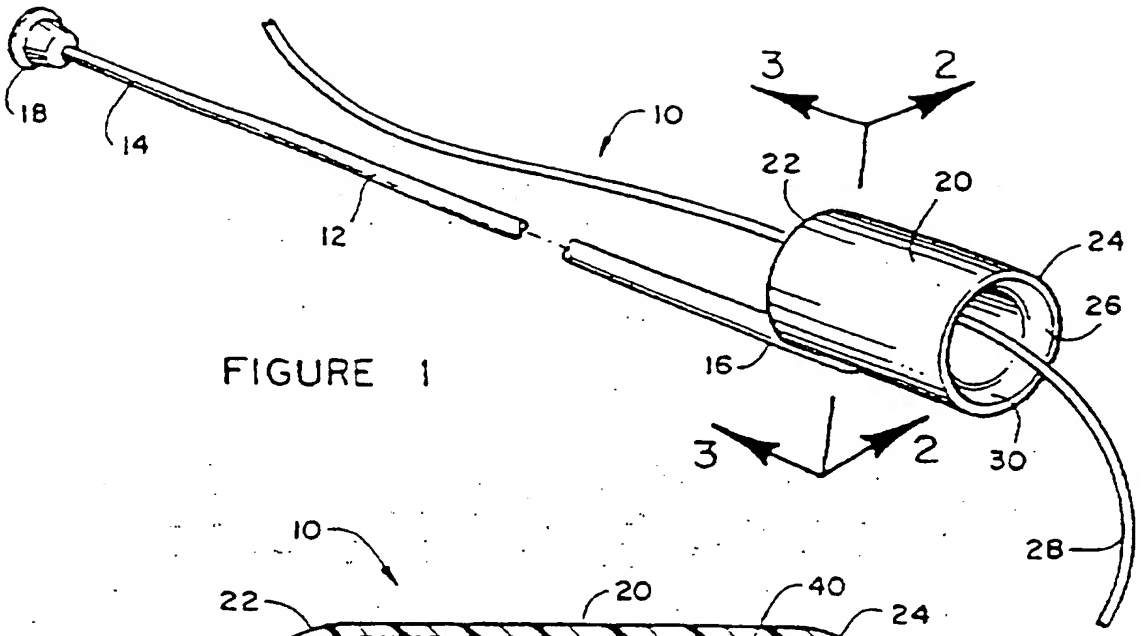


FIGURE 1

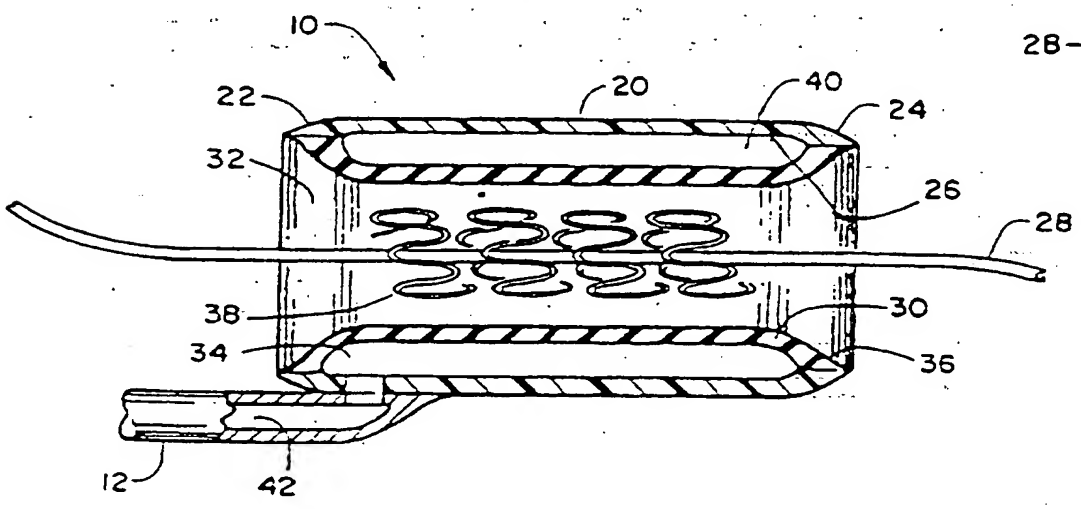


FIGURE 2

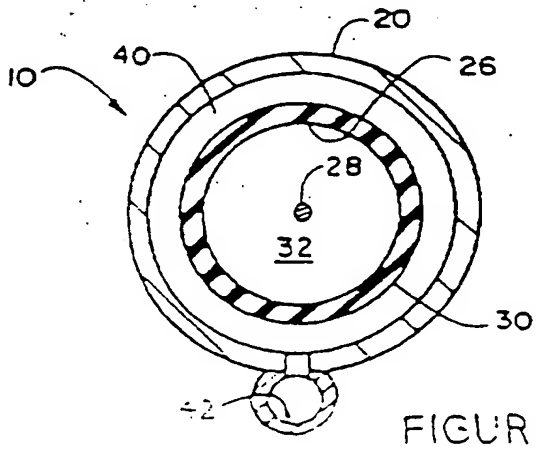


FIGURE 3

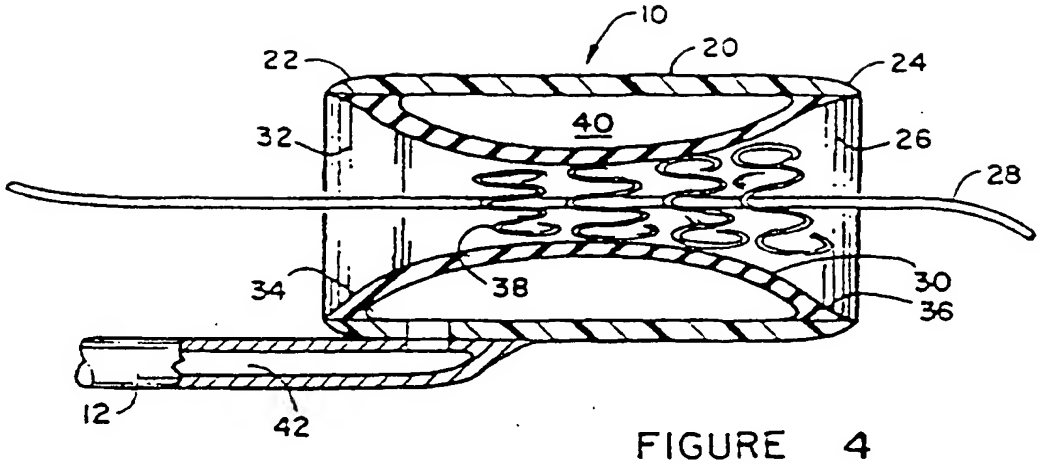


FIGURE 4

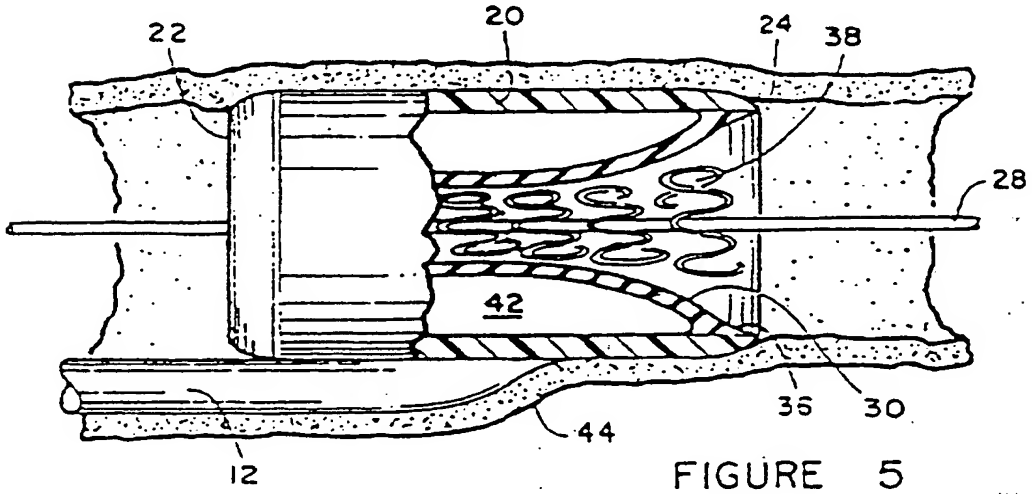


FIGURE 5

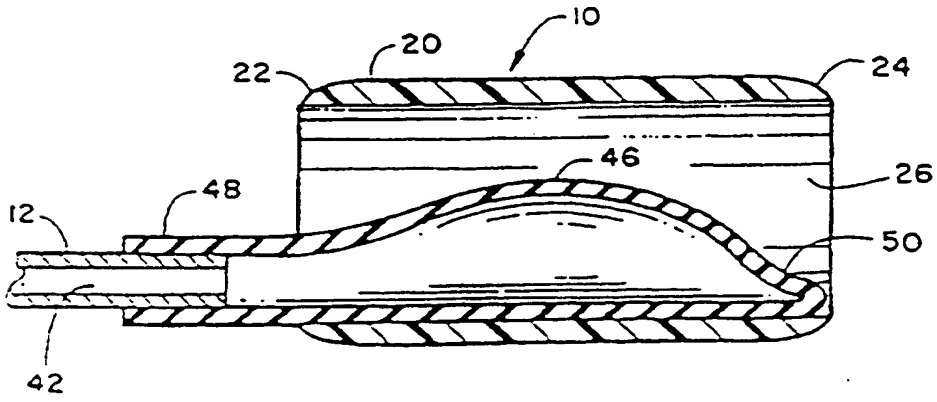


FIGURE 6

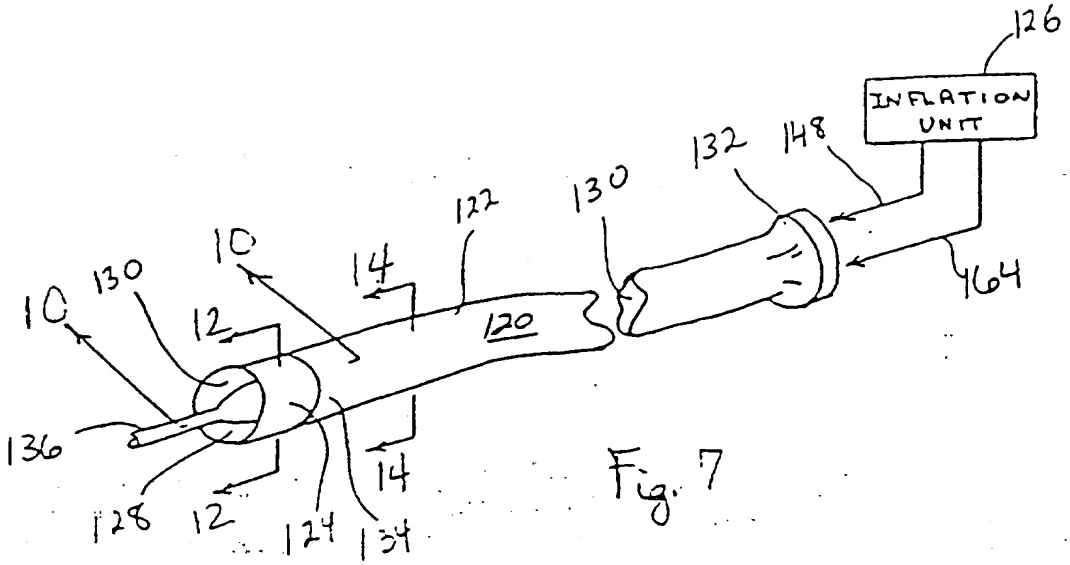


Fig. 7

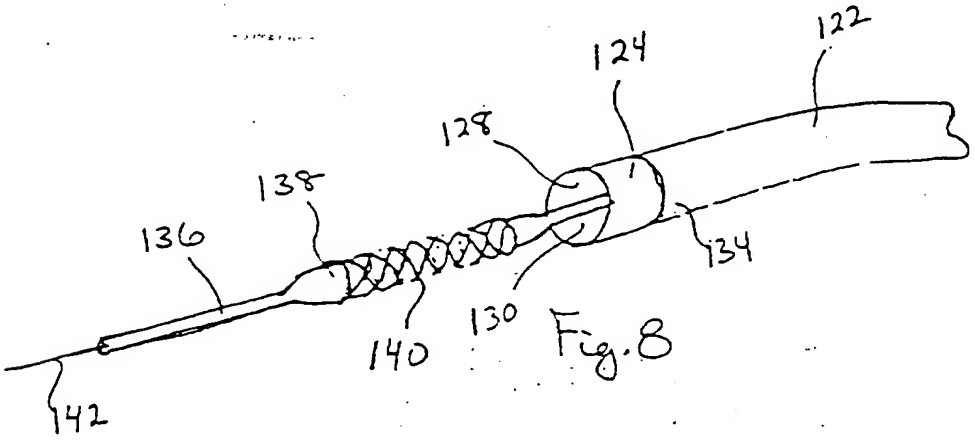


Fig. 8

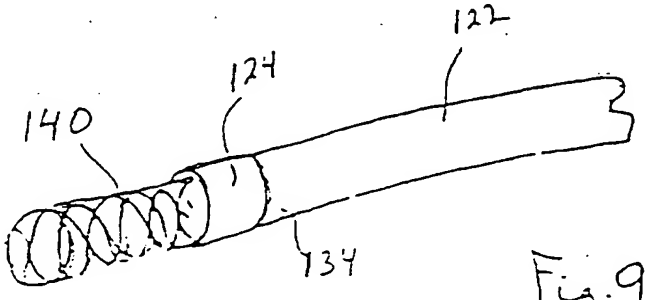


Fig. 9

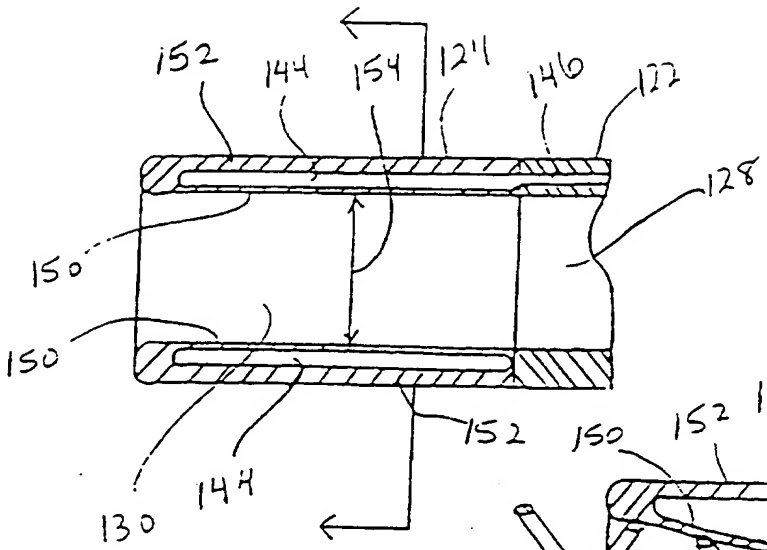


Fig. 10

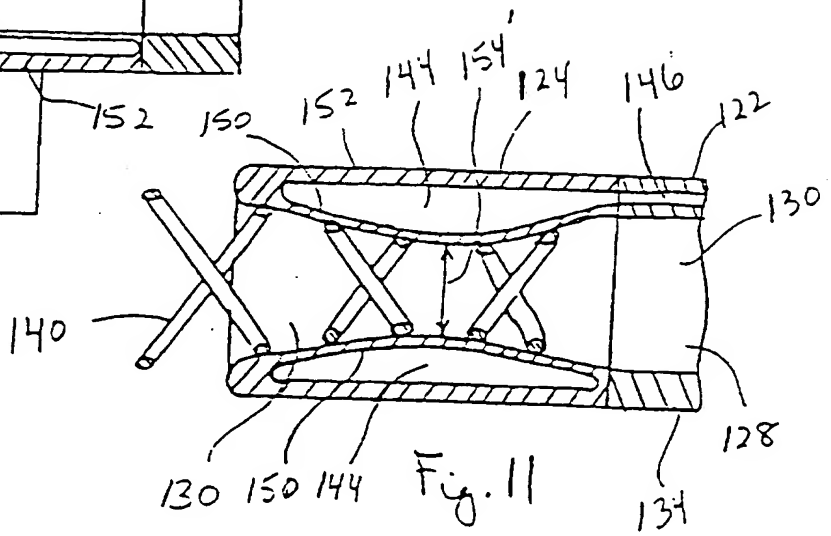


Fig. 11

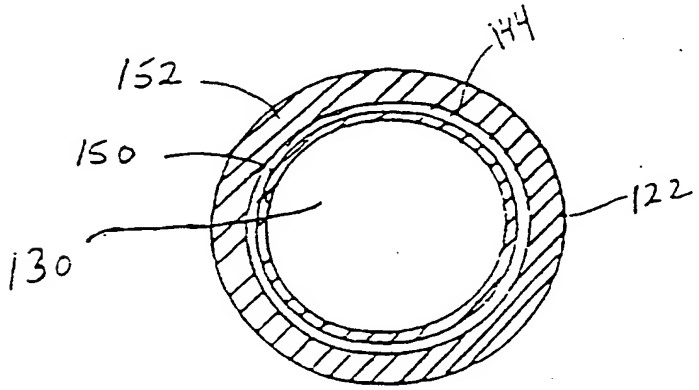


Fig. 12

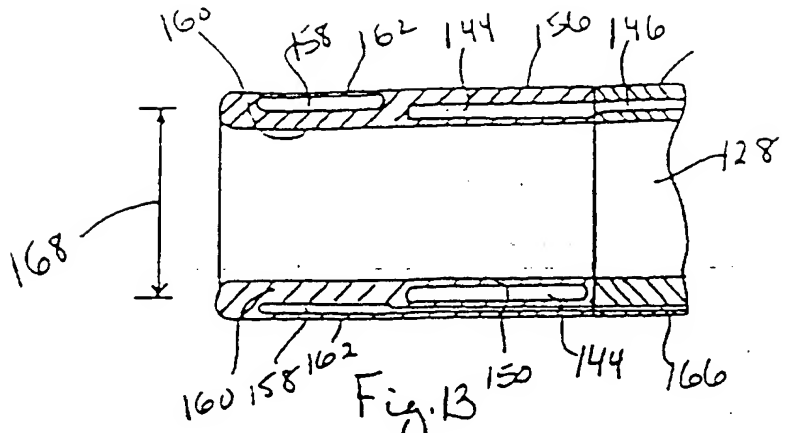


Fig. 13

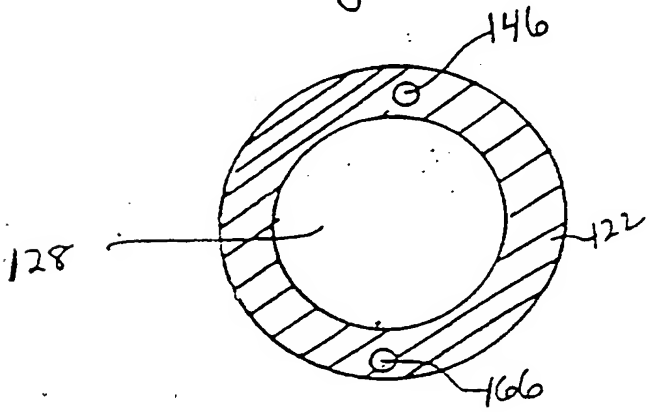


Fig 14

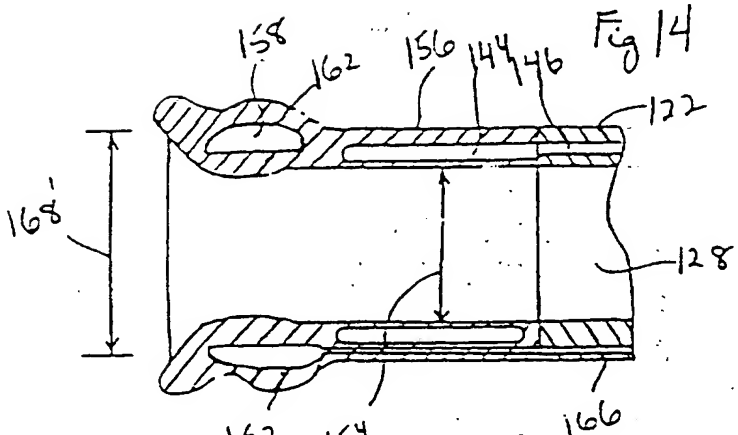


Fig. 15

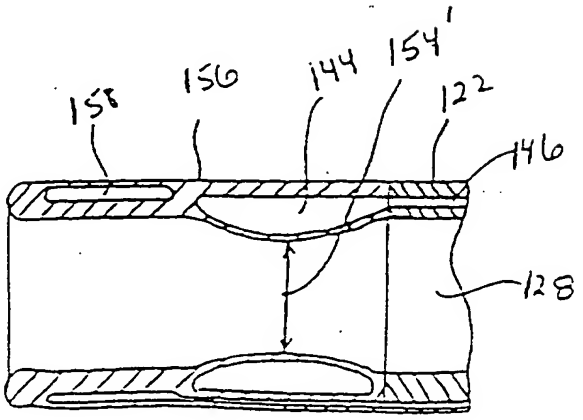


Fig 16

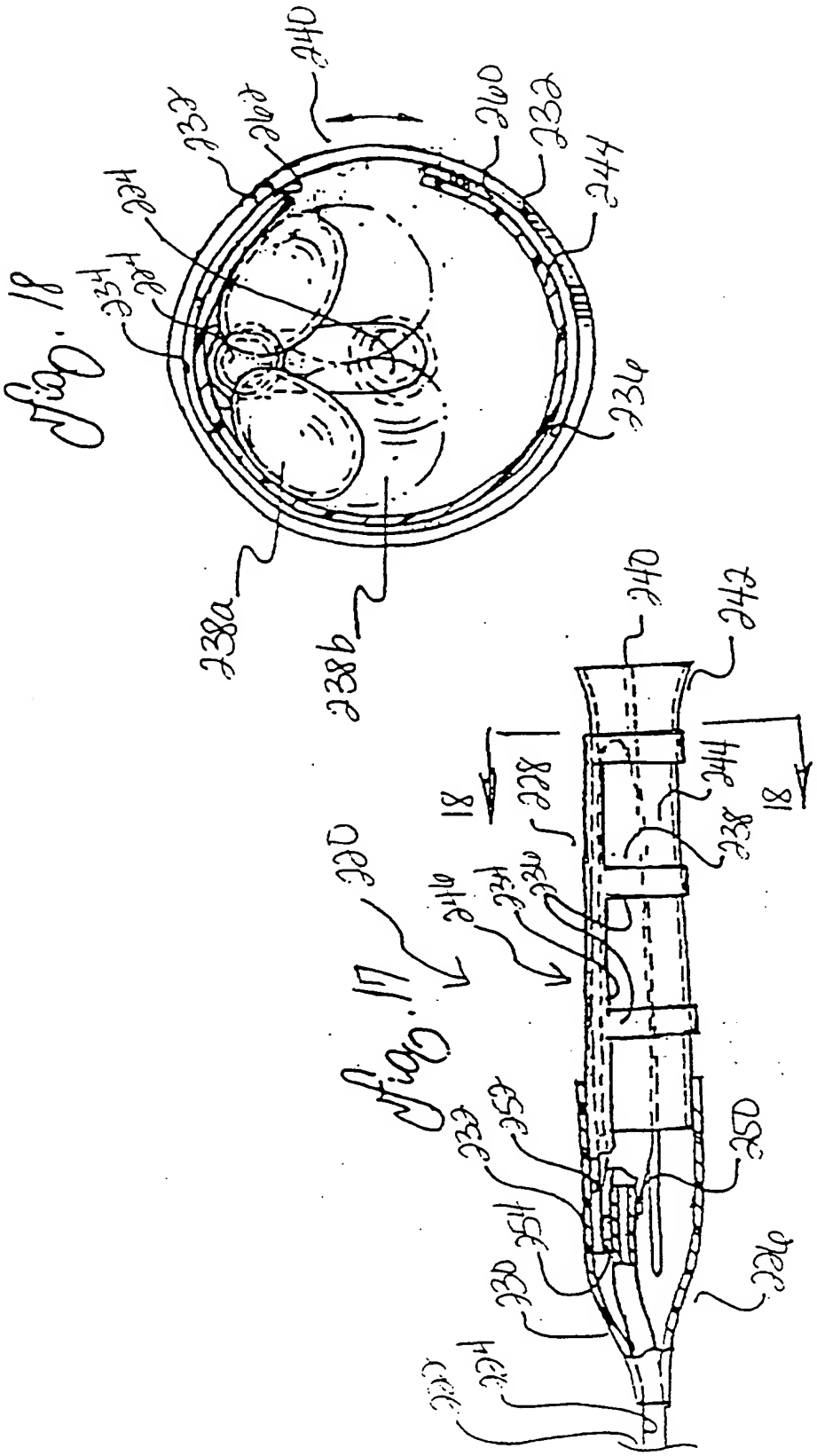


Fig. 19

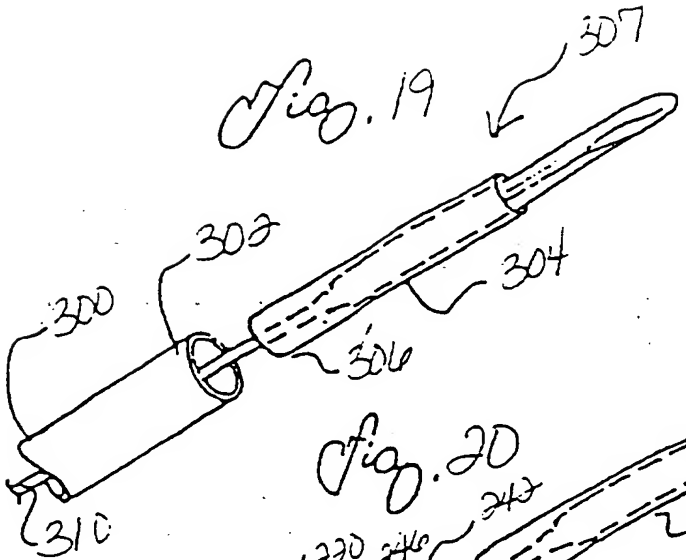


Fig. 20

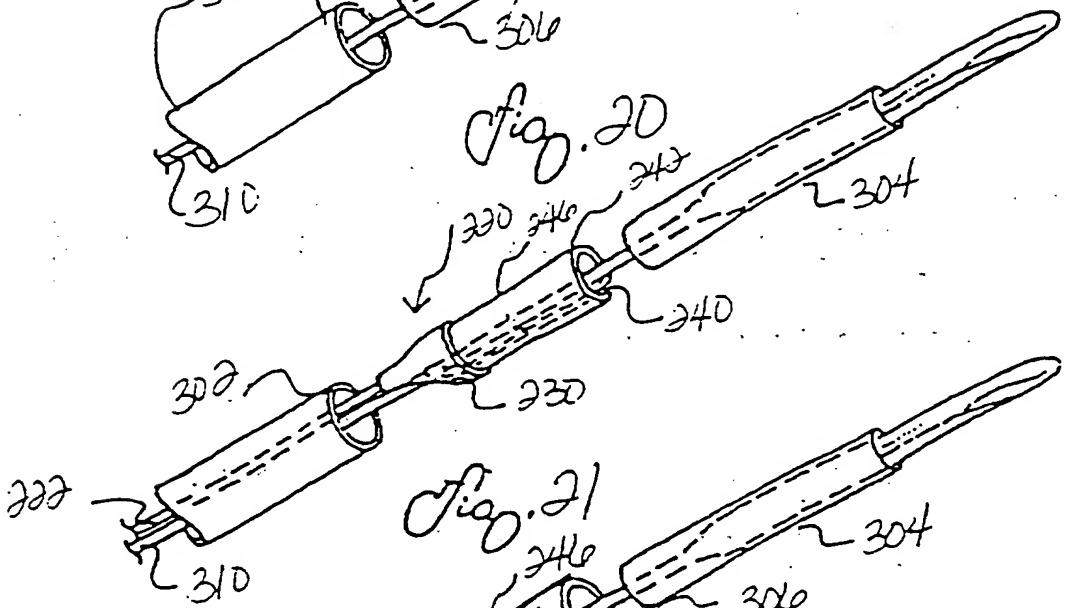


Fig. 21

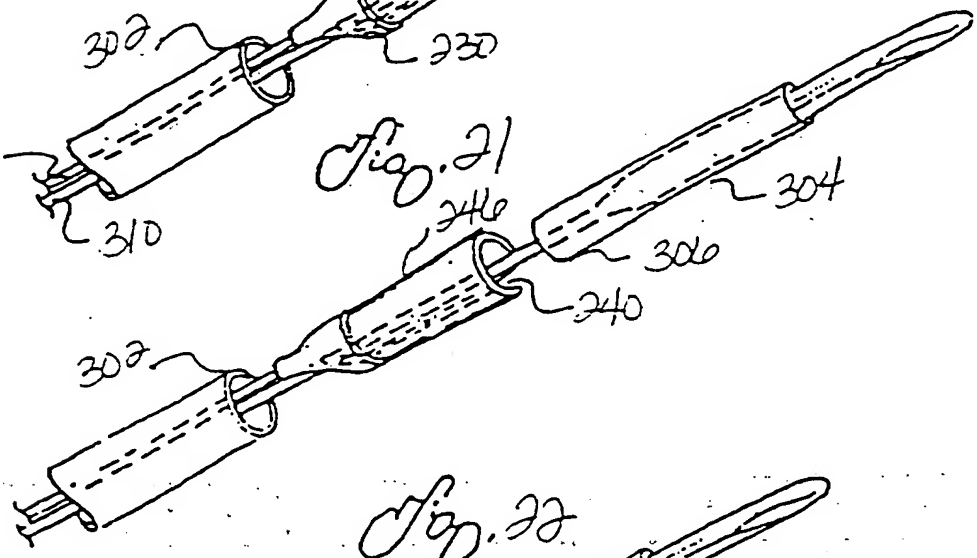
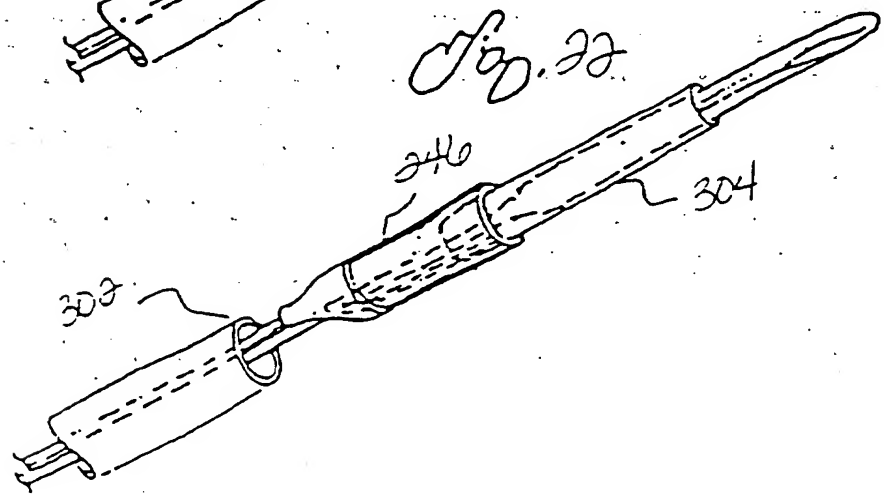


Fig. 22



INTERNATIONAL SEARCH REPORT

Ir. tional Application No
PCT/US 96/18319

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 594 996 A (IBRAHIM ADEL A ET AL) 17 June 1986 see the whole document ---	1,2,4,5, 7,9,11, 12,16 3,4,6,8, 10, 13-15, 17-20, 27,33, 37-39,45
A	DE 21 04 673 A (VEB KOMBINAT MEDEZIN- UND LABORTECHNIK) 31 May 1972 see the whole document --- -/--	1,2,7, 13,16, 17,33, 37,39,45

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
10 March 1997	17. 03. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Vereist, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/18319

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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Information on patent family members

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